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obtained with cell culture combined with immunofluorescence [15], while sensitivities obtained with rapid diagnostic immunoassays for influenza A vary from 75% [16,17] to 100% [8,16,18].

It is accepted widely that PCR techniques are superior to EIAs with regard to sensitivity and specificity [18]. For a diagnosis when the prevalence of acute respiratory tract infection is low, i.e., outside the yearly epidemic season, EIAs have a low PPV, and thus their use in diagnosis is questionable. More accurate techniques, such as PCR, should be used in diagnosis of virus respiratory tract infections for epidemiological research and intervention trials.

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RESEARCH NOTE

Comparative evaluation of TRI-DOT Rapid HIV test with fourth-generation ELISA for the detection of human immunodeficiency virus

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ABSTRACT

This study evaluated the TRI-DOT Rapid HIV test for the early detection of human immunodeficiency virus (HIV) infection in comparison with a fourth-generation ELISA (Vironostika HIV Uniform II). Of 23 609 sera, seven (0.03%) gave discordant results. Six of these were reactive only by the fourth-generation assay and were p24 antigen-positive by VIDAS DUO, Western blot and qualitative RT-PCR tests. The remaining discordant serum was considered to be false-positive by the TRI-DOT assay, as it was negative by repeat ELISA and Western blot tests. The sensitivity and specificity of the TRI-DOT test were 99.48% and 99.99%, respectively, compared with the fourth-generation ELISA.

Keywords Detection, fourth-generation ELISA, human immunodeficiency virus, p24 antigen, Rapid assay TRI-DOT

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Early knowledge of human immunodeficiency virus (HIV) serostatus is an important element in HIV prevention and treatment. Laboratory methods for screening blood from HIV-infected individuals can be classified into those that detect antibody, identify antigen, monitor virus nucleic acid or provide an estimate of CD4 cell counts [1]. Ideally, to maximise the detection of all infected individuals, especially during the period following exposure or in the early stages of infection before antibody is detectable, antigen and virus RNA tests should be used. As virus RNA tests are expensive, time-consuming, and not available in many laboratories, fourth-generation ELISAs have been designed to detect anti-HIV immunoglobulin and HIV core protein p24 antigen simultaneously in order to screen for both the early and late phases of infection. These new ELISAs have the advantage of decreasing the diagnostic window (mean reduction of 4–7 days), personnel and costs in comparison with the requirements for performing each assay individually [2–9]. The detection of early infection has been shown to be beneficial for the initiation of treatment and counselling of infected individuals, and for the institution of interventions to reduce the risk of further transmission.

With the introduction in India of the concept of point-of-care testing and Voluntary Counselling and Testing Centres, several rapid tests for HIV have been developed that are low-cost and easy to perform. Several previous reports have compared fourth- and third-generation ELISAs [5–9], or two or more rapid HIV tests [10,11], but there are few reports that compare the performance of rapid HIV tests with fourth-generation ELISAs for the detection of HIV in patients' sera. As >30% of HIV tests in our institute are requested for emergency purposes, and are thus rapid HIV tests, the present study evaluated the TRI-DOT Rapid HIV flow-through test (Mitra & Co., New Delhi, India) in comparison with a fourth-generation ELISA (Vironostika HIV Uni-Form II Ag/Ab; bioMérieux, Marcy l'Etoile, France) for the early detection of HIV infection.

Between January 2003 and April 2004, 23 609 sera were received from various units of our institute for HIV testing. Rapid HIV testing using the TRI-DOT kit was requested for 7913 (33.5%) of these sera because of various emergency situations. This kit is a flow-through device with an inbuilt internal control and two separate antigen dots for HIV-1 and HIV-2. All these sera, irrespective of their HIV status, were also retested by the fourth-generation ELISA Vironostika HIV Uni-Form II Ag/Ab assay. The remaining 15 696 'routine' sera were screened with the fourth-generation ELISA, and were retested with the TRI-DOT kit. Both test procedures were performed according to the manufacturers' instructions. For the calculation of sensitivity and specificity, sera were considered to be 'true-positives' when they were positive by both assays. In the case of discordance, sera were retested by Western blot (General Biological Corporation, Taipei, Taiwan), the VIDAS HIV DUO assay (bioMérieux), and qualitative RT-PCR (Amplicor HIV-1; Roche Diagnostics, Mannheim, Germany). Samples were considered non-reactive when both the TRI-DOT and ELISA tests were negative.

Of 23 609 sera tested, 22 459 (95.1%) were non-reactive, and 1145 (4.8%) were positive by both assays. There were seven (0.03%) discordant sera, of which six were reactive only by the fourth-generation ELISA and were Western blot-negative, but were p24 antigen-positive by the VIDAS HIV DUO assay; thus they could not be detected by the TRI-DOT assay. Four of these six sera were also positive by qualitative RT-PCR, while the

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remaining two could not be assayed by RT-PCR. One discordant sample that was reactive only by the TRI-DOT assay was non-reactive by repeat ELISA, Western blot, VIDAS DUO and RT-PCR; this was considered to be a false-positive result by the TRI-DOT kit. Thus, compared with the fourth-generation ELISA, the TRI-DOT Rapid HIV test had a specificity of 99.9% and a sensitivity of 99.5%. The overall prevalence of HIV-1 and HIV-2 in the sera studied was 4.7% and 0.2%, respectively, and 19 (1.7%) of the 1150 HIV-positive patients were infected with both HIV-1 and HIV-2.

The CDC has advocated routine testing of patients for HIV as a means of increasing provider vigilance and reducing occupational exposure [12]. The results are also helpful in making patients aware of their infection and enabling appropriate treatment and counselling [12,13]. Early diagnosis of HIV infection is the cornerstone of prevention and care strategies for HIV-infected individuals. The rapid test used in the present study only detects HIV antibodies, and not the p24 antigen; thus there is always the possibility of missing a recent infection when the p24 antigen is present, but without any detectable antibody levels. The results of the study indicated that the TRI-DOT HIV test failed to detect only six (0.5%) of 1150 reactive sera; these six sera were presumably from patients who were in the early stages of infection. Thus the TRI-DOT HIV Rapid assay, which gives a result within 10 min, can be used in emergency situations when there is insufficient time to perform a fourth-generation ELISA. However, the results should later be confirmed by ELISA to rule out the possibility of early infection. The two tests showed good sensitivity for both HIV-1 and HIV-2.

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RESEARCH NOTE

Seasonal variations in acute toxoplasmosis in pregnant women in Slovenia

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